

OFFICE OF WATER CYANOTOXIN HEALTH EFFECTS SUPPORT DOCUMENT PEER REVIEW HISTORY

Initially, information on the three cyanotoxins, anatoxin-a, microcystin, and cylindrospermopsin, were included in a single Health Effects Support Documents (HESD). The combined HESD underwent an external letter peer review in February 2014 (peer review #1). As a result of the external peer review comments received during this peer review, HESD documents were developed separately for each of the three cyanotoxins. Each HESD includes a comprehensive review of the published literature on occurrence and sections on environmental fate; mechanisms of toxicity; acute, short term, subchronic and chronic toxicity and cancer in humans and animals; toxicokinetics; health effects and exposure. The HESD also provides a dose-response assessment for the development of a reference dose (RfD) where the peer reviewers advised this. The peer reviewers agreed that the data for microcystins and cylindrospermopsin were adequate to develop health advisory values, but they did not conclude that data for anatoxin-a were adequate to support development of a health advisory value. Accordingly, two HESDs were developed for microcystins and cylindrospermopsin.

The HESD for cylindrospermopsin underwent an additional letter peer review. The second peer review was finalized in October 2014 (peer review #2a). Based on the comments received, EPA determined that adequate data are available to develop a guideline value and that no additional peer review was necessary.

The HESD for microcystins underwent two additional letter peer reviews following the first peer review. The second peer review was finalized in October 2014 (peer review #2b). There was considerable diversity in the peer reviewers evaluation of the critical study used as the basis for development of the RfD for microcystins. Specifically, most did not support the use of the reproductive toxicity study by Chen et al. (2011), citing limitations including the methodology used and deficiencies in the reporting of data. As a result of this peer review, EPA selected a short-term exposure study (28 days) as the critical study to develop the RfD for microcystins. The third letter peer review of the HESD for microcystins focused on the quantification of risk based on the short-term study (Heinze 1999) was finalized in February 2015 (peer review #3).

In April 2015, it came to EPA's attention that one of the peer reviewers of the original HESD (peer review #1), Dr. Marc Odin, was also listed as an author of a draft Toxicological Review produced by the Office of Research and Development at EPA which was utilized in the development of the HESDs. This document was a revision of a draft 2007 document that was peer reviewed, but the document was not finalized by EPA. In light of this situation, Dr. Odin was added to the list of authors of the HESDs and his comments were removed from the consolidated peer review report. Because the peer reviewers did not meet and discuss their comments, the comments of the remaining two peer reviewers are not affected by this situation.

The health advisories (HA) for microcystins and cylindrospermopsin were developed using these peer reviewed data and standard methodology used by EPA to derive HAs.